

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Date: September 15, 1999
From: Hany Demian, M.S.
Executive Secretary, Orthopaedics and Rehabilitation Devices Advisory Committee
To: Panel Members
Subject: Contents of This Mailing

Panel Members:

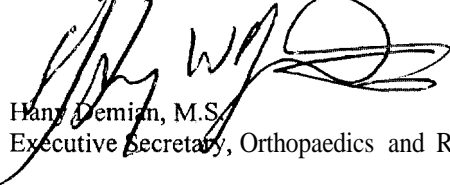
This memo is intended to describe the contents of this mailing. This shipment includes:

- FDA Panel Pack:
 - Tab 1: Panel Questions: Panel members should be prepared to address each panel question at the meeting.
 - Tab 2: Review Memo from Lead Reviewer dated September 15, 1999
 - Tab 3: Review Memos from Statistical Reviewer dated September 15 and June 28, 1999
- Petition for Reclassification for Constrained Total Hip Systems: 2 Volumes

This information is intended to provide you with sufficient details to allow for an objective and focused review of the petition.

If you **have** any questions regarding the contents of **this** package or your responsibilities during the panel meeting, please feel free to contact me via either e-mail (hwd@cdrh.fda.gov) or by phone (301-594-2036 extension 184).

Sincerely,



Hany Demian, M.S.
Executive Secretary, Orthopaedics and Rehabilitation Devices Advisory Committee